

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

CU-2481 RJS

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

09/787171

INTERNATIONAL APPLICATION NO.

PCT/SE99/01608

INTERNATIONAL FILING DATE

15 September 1999

PRIORITY DATE CLAIMED

15 September 1998

TITLE OF INVENTION

HALLUX VALGUS BRACE

APPLICANT(S) FOR DO/EO/US

Jan F.A. SMITS

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)).
4. ☒ The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 16 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A ~~FIRST preliminary amendment~~ Request for Examination of Application
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☐ Other items or information:

Express Mail Label No.:

L 698 1802 91

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17. ☒ The following fees are submitted:**BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):**

Neither international preliminary examination fee (37 CFR 1.482)
nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO
and International Search Report not prepared by the EPO or JPO \$1000.00

International preliminary examination fee (37 CFR 1.482) not paid to
USPTO but International Search Report prepared by the EPO or JPO \$860.00

International preliminary examination fee (37 CFR 1.482) not paid to USPTO but
international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$710.00

International preliminary examination fee paid to USPTO (37 CFR 1.482)
but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$690.00

International preliminary examination fee paid to USPTO (37 CFR 1.482)
and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00

ENTER APPROPRIATE BASIC FEE AMOUNT =**CALCULATIONS** PTO USE ONLY

JG08 Rec'd PCT/PTO 14 MAR 2001

\$ 1000.00

Surcharge of \$130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30
months from the earliest claimed priority date (37 CFR 1.492(e)).

\$

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	10 - 20 =	0	X \$18.00
Independent claims	1 - 3 =	0	X \$80.00

\$ 270.00

MULTIPLE DEPENDENT CLAIM(S) (if applicable)

+ \$270.00

TOTAL OF ABOVE CALCULATIONS =

\$ 1270.00

☒ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above
are reduced by 1/2.

\$ 635.00

SUBTOTAL =

\$ 635.00

Processing fee of \$130.00 for furnishing the English translation later than ☐ 20 ☐ 30
months from the earliest claimed priority date (37 CFR 1.492(f)).

\$

TOTAL NATIONAL FEE =

\$

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be
accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property

\$

TOTAL FEES ENCLOSED =

\$ 635.00

Amount to be
refunded:
charged: \$

a. ☒ A check in the amount of \$ 635.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any
overpayment to Deposit Account No. 12-0400. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Ladas & Parry
224 South Michigan Avenue
Suite 1200
Chicago, Illinois 60604
(312) 427-1300

March 14, 2001

SIGNATURE

Richard J. Streit

NAME

25765

REGISTRATION NUMBER

2/PRTS

WO 00/15163

PCT/SE99/01608

HALLUX VALGUS BRACEField of the invention

The present invention relates to a hallux valgus brace, i.e. a brace designed
5 for treatment of non-rigid hallux valgus. The complete brace is positioned in front
of the metatarsal joint and can be used during walking and other activities.

State of the art

Hallux valgus is a painful malposition of the big toe, where the big toe turns
10 towards the other toes and a bunion is formed on the protruding joint, i.e. the first
metatarsal joint. This deformity has been treated in the past mainly by means of
night splints or braces. The brace is mainly used during sleeping or resting. The
brace uses three pressure points, two of which are located at the metatarsus. Thus,
15 the prior art brace requires support proximal of the metatarsal joint. The brace
bridges the metatarsal joint resulting in that the brace is not suitable for walking
because the bending of the joint together with the brace is not comfortable or even
impossible.

The present invention solves this problem by positioning the complete brace
distally of the metatarsal joint. Thus, all components of the brace are located
20 distally of the metatarsal joint and the brace is not affected by the bending of the
joint during walking and other activities. In this way, the brace of the invention
may be used for conservative dynamic treatment of non-rigid hallux valgus. In
other words, the patient may wear the brace practically at all times resulting in an
efficient treatment.

Summary of the invention

Thus, the present invention provides a hallux valgus brace comprising a
three point lever means for correcting the position of the big toe.

According to the invention the complete brace is designed to be located
30 distally of the metatarsal joint. Preferably, the brace comprises a proximal pad
pressing on the medial side on the first phalanx of the big toe, a distal pad pressing
on the distal end of the first phalanx, and a lever arm pressing on the ball of the
foot.

The invention is defined in claim 1 while preferred embodiments are set
35 forth in the dependent claims.

Brief description of the drawings

The invention will be described in detail below with reference to the accom-
panying drawings in which:

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figure 1 is a bottom view of the brace on the foot of a patient;
figure 2 is a detail view of one component of the brace carrying the distal
pad;
figure 3 is a detail view of the main part of the brace; and
5 figure 4 is a bottom view of the complete brace according to the invention.

Detailed description of preferred embodiments

The hallux valgus brace according to the invention is now described with
reference to the drawings. In figure 1, the brace is shown as worn by a patient on a
10 foot. The skeletal bones of the foot are shown for reference. In figure 4, the
complete brace 1 is shown by itself. The brace is located in the space which exists
under the normally slightly bent toes. At the medial side the brace carries a
proximal pad 2 pressing on the first phalanx of the big toe. A distal pad 3 is carried
by an adjustable arm 5 and presses on the distal end of the big toe, preferably on
15 the distal end of the first phalanx.

The pads 2 and 3 are connected to the frame of the brace by means of
hinges, so that the pads can turn and adapt themselves to the curvature of the
contact area between the pads and the toe. Thus, the pads 2 and 3 are self-adjusting
for better fit and comfort.

20 The lateral part of the brace comprises a lever arm 4 pressing backwards and
acting as a counterforce on the ball of the foot. The lever arm 4 also carries a strap
8, best shown in figures 3 and 4. Another toe is inserted through the strap 8 serving
to prevent the lever arm 4 from sliding down. This is preferably the third toe since
this toe is a little longer and stronger but also e.g. the fourth toe could be used.

25 The adjustable arm 5 is connected to the main part of the brace by means of
a sleeve 6. The sleeve 6 may be slid to a correct position in order to accommodate
various sizes of big toes. When the sleeve 6 is positioned correctly it may be fixed
with glue.

30 The brace is manufactured from stainless steel spring-wire, thickness e.g.
1,75 mm. The pads 2 and 3 are cup shaped pads, made of steel sheet, thickness e.g.
0,6 mm or injection moulded plastic. The adjustable sleeve 6 is also preferably
made of stainless steel.

35 For best comfort the lever arm 4 may carry a silicone tube 7. The strap 8 is
suitably made of rubber or plastic, but may also be made of leather, cotton or a
hook and loop connection (Velcro® fastening).

The distal pad 3 may carry another strap or fastening means 9 to be
located around the big toe and preventing the pad from sliding off. This strap 9
suitably comprises a hook and loop connection for easy fastening and adjustment.

The brace according to the invention can be used in a dynamic way. Since

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all correcting and stiff parts are located distally of the metatarsal joint the brace does not interfere with normal walking. The brace has a lever means with a clear three point working principle. A force A on the medial side moves the first phalanx laterally while a force B on the lateral side moves the distal end of the first phalanx and the toe medially. The reaction force C is applied against the soft tissue of the ball of the foot.

For the brace of the invention to be efficient the first metatarsal joint needs to be flexible enough to be repositioned and flexed in a horizontal plane. The patient should wear a shoe or slipper providing sufficient room for the medial movement of the toe.

The brace according to the invention is intended to be delivered as an "of the shelf" item and requires adjustments before it can be worn by a patient. Thus, the wire parts of the brace are bent for a proper fit. The sleeve 6 is positioned correctly and preferably glued to secure it to the wire. It is suitable that this work is performed by an orthotist/bandagist or possibly a podiatrist, even if patients eventually may learn to fit the braces themselves.

Thus, the present invention provides several advantages over the prior art. The brace allows for a dynamic treatment since the brace may be used at all times during walking, resting etc. and in normal shoes. The brace is adaptable for various foot sizes by means of some simple adjustments only. The brace is very light-weight and very comfortable.

A person skilled in the art will appreciate that the brace of the invention may be modified without departing from the scope of the invention. Thus, the embodiment shown is just given as an example of shapes and materials that may be used. The scope of the invention is only limited by the claims below.

27-03-2000

CLAIMS

1. A hallux valgus brace comprising a three point lever means for correcting the position of the big toe, **characterised** in that the brace (1) including the three point lever means is designed to be located distally of the metatarsal joint, wherein
5 the three points of the lever means are one point (A) on the medial side of the first phalanx of the big toe, one point (B) on the lateral side of the distal end of the big toe, and one point (C) on the ball of the foot.
2. A brace according to claim 1, **characterised** in that the brace (1) comprises a proximal pad (2) pressing (A) on the first phalanx of the big toe, a
10 distal pad (3) pressing (B) on the distal end of the big toe, and a lever arm (4) pressing (C) on the ball of the foot.
3. A brace according to claim 2, **characterised** in that the distal pad (3) is adapted to press (B) on the distal end of the first phalanx of the big toe.
4. A brace according to claim 2 or 3, **characterised** in that the distal pad (3)
15 is disposed on an adjustable arm (5).
5. A brace according to claim 4, **characterised** in that the adjustable arm (5) is secured to a sleeve (6) which is slidable and may be fixed with glue.
6. A brace according to any one of the preceding claims, **characterised** in that the brace is manufactured from steel wire and steel pads.
- 20 7. A brace according to any one of claims 2-6, **characterised** in that the lever arm (4) is provided with a silicone tube (7).
8. A brace according to any one of the preceding claims, **characterised** in that a strap (8) is provided for fitting around the third toe.
9. A brace according to claim 7, **characterised** in that the strap (8) is made
25 of rubber or plastic or a hook and loop connection.
10. A brace according to any one of the preceding claims, **characterised** in that the distal pad (3) carries a strap (9) to be located around the big toe.

AMENDED SHEET

09787171-060603
T090909 T2728260

ABSTRACT

The invention relates to a hallux valgus brace, i.e. a brace designed for treatment of non-rigid hallux valgus. The brace comprises a three point lever means for correcting the position of the big toe. According to the invention the complete brace is designed to be located distally of the metatarsal joint. Preferably, the brace comprises a proximal pad pressing on the first phalanx of the big toe, a distal pad pressing on the distal end of the first phalanx of the big toe, and a lever arm pressing on the ball of the foot. The brace can be used during walking and other activities.

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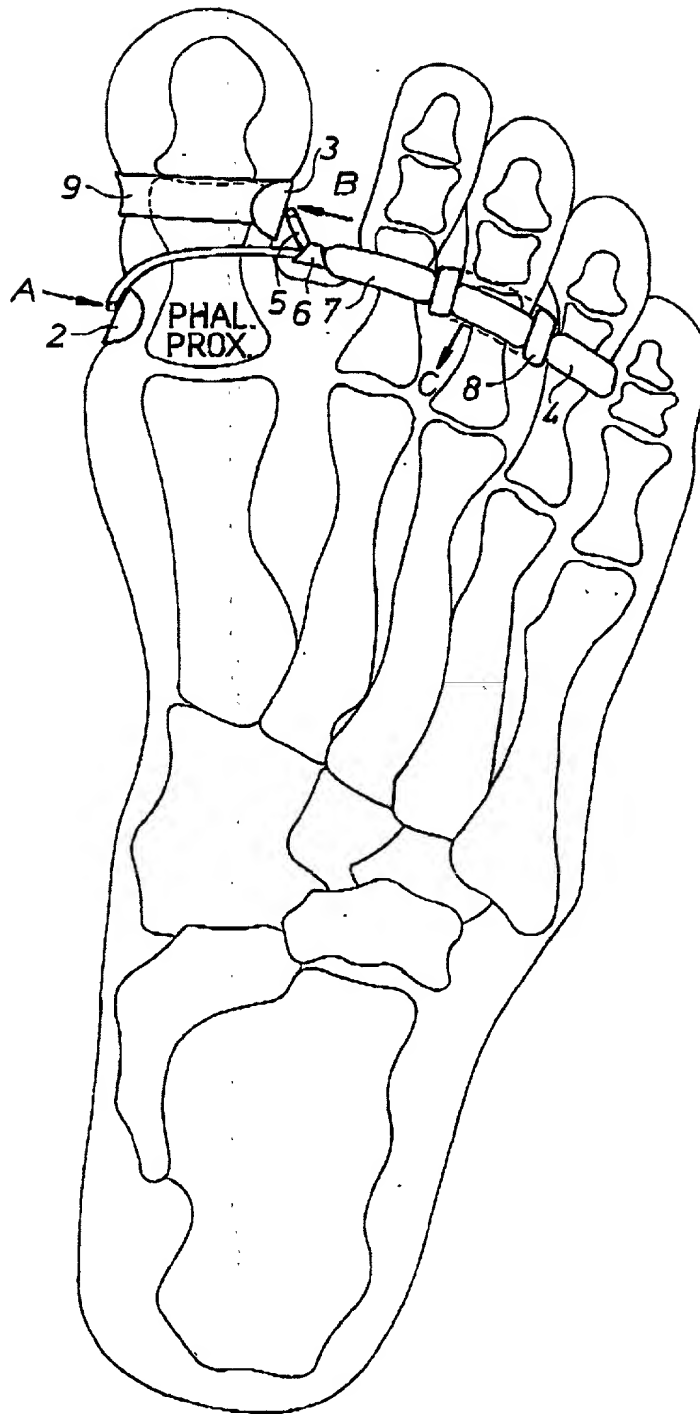


FIG. 1

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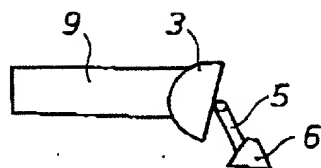


FIG. 2

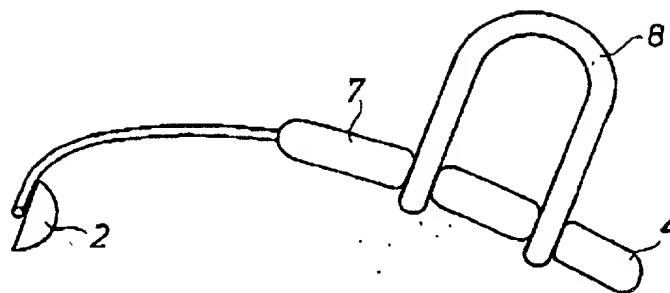


FIG. 3

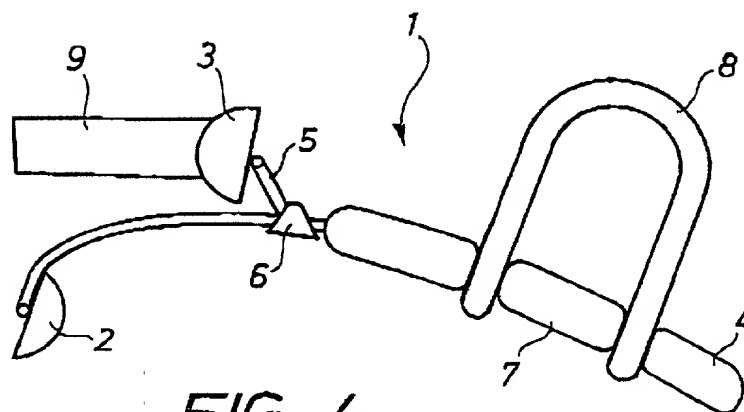


FIG. 4

Docket: CU-2481

COMBINED DECLARATION AND POWER OF ATTORNEY(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,
CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: (check one applicable item below)

- ☐ original
☐ design
☐ supplemental

Note: If the Declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application, do not check next item; check appropriate one of last three items.

- ☒ national stage of PCT

Note: If one of the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.

- ☐ divisional
☐ continuation
☐ continuation-in-part (CIP)

INVENTORSHIP IDENTIFICATION

WARNING: If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

HALLUX VALGUS BRACE

SPECIFICATION IDENTIFICATION

the specification of which: (complete (a), (b) or (c))

- ☐ (a) is attached hereto.
☐ (b) was filed on _____ as ☐ Serial No. _____ or ☐ Express Mail No. (as Serial No. not yet known) _____ and was amended on _____ (if applicable).

Note: Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded a filing date by being referred to in the Declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental Declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.

- ☒ (c) was described and claimed in PCT International Application No. PCT/SE99/01608 filed on 15 September 1999 and as amended under PCT Article 19 on _____ (if any).

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ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56,

(also check the following items, if desired)

- ☐ and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and
- ☐ in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 CFR 1.98.

PRIORITY CLAIM (35 U.S.C. § 119(a)-(d))

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

- ☐ (d) no such applications have been filed.
- ☒ (e) such applications have been filed as follows.

Note: Where item (c) is entered above and the international application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day/month/year)	PRIORITY CLAIMED UNDER 35 USC 119
Sweden	9803110-7	15 September 1998	<input checked="" type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) (34 U.S.C. § 119(e))

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER	FILING DATE

ALL FOREIGN APPLICATION(S), IF ANY, FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

Note: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CIP APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. § 120.

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith (list name and registration number).

Thomas F. Peterson, 24790; Richard J. Streit, 25765; Donald P. Reynolds, 26220; W. Dennis Drehkoff, 27193; Vangelis Economou, 32341; Brian W. Hameder, 45613; Paul B. West, 18947; Joseph H. Handelman, 26179; Peter D. Galloway 27885; John Richards, 31503; Iain C. Baillie, 24090; Richard P. Berg, 28145

☐ Attached, as part of this declaration and power of attorney, is the authorization of the above-named practitioner(s) to accept and follow instructions from my representative(s).

SEND CORRESPONDENCE TO:

Thomas F. Peterson
c/o Ladas & Parry
224 South Michigan Avenue
Suite 1200
Chicago, Illinois 60604

DIRECT TELEPHONE CALLS TO:

(Name and telephone number)

(312) 427-1300

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

Note: Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other documents.

Full name of sole or first inventor

100 Jan F.A. SMITS
(Given Name) (Middle Initial or Name) (Family (or Last) Name)
Inventor's signature [Signature]
Date 21-04-001 Country of Citizenship Netherlands
Residence Helmond, The Netherlands NLX
Post Office Address Holterbergweide 26, NL-5709 MP Helmond, The Netherlands